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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SYED F.A. HOSSAINY

Appeal 2009-005482
Application 10/815,421
Technology Center 1600

Decided: February 16, 2010

Before DEMETRA J. MILLS, ERIC GRIMES, and MARK NAGUMO
Administrative Patent Judges.

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claim is representative.

31. A medical article comprising an implantable medical device and a coating deposited on at least a part of the device, the coating including:

- (a) a structural component comprising a linear acrylic homopolymer or linear acrylic copolymer; and
- (b) a biobeneficial component comprising a copolymer having an acrylate moiety and a biobeneficial moiety.

Cited References

Whitbourne et al.	US 6,110,483	Aug. 29, 2000
Pacetti et al.	WO 2004/101018 A1	Nov. 25, 2004

Grounds of Rejection

Claims 31-41, 47-49, 51 and 52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitbourne in view of Pacetti.

FINDINGS OF FACT

1. The Office Action dated October 12, 2007, page 3, states that the elected species embodiment, poly(ethylene glycol)-co-PBMA-co-poly(ethylene glycol), PEG-PBMA-PEG, is entitled to an effective filing date of March 31, 2004.
2. Appellant's Statement of Common Ownership filed January 9, 2008, refers to "the current application (U.S. Serial No. 10/750,139)" which is incorrect, as the pending application has "Serial No. 10/815,421."
3. The Examiner finds that the claims require a medical device, specifically a stent, with a two-part coating. (Ans. 3.)

4. “The coating must contain a structural component, for which Applicants elected PBMA (poly (butyl methacrylate)), and a biobeneficial component, for which Applicants elected [poly(ethylene glycol)-co-PBMA-co-poly(ethylene glycol)].” (*Id.* at 3-4.)
5. “Whitbourne teaches stents coated with PBMA (claim 7).” (*Id.* at 4.)
6. “Whitbourne does not teach the use of PEG-PBMA-PEG.” (*Id.*)
7. The Examiner finds that

The WO reference [Pacetti] teaches the use of PBMA and PEG as a topcoat for a polymer coated stent (examples 4 and 5). The PEG and PBMA form an interpenetrating polymer mixture, which suffices to read on the elected PEG-PBMA-PEG block copolymer according to Applicants' definition of block copolymer in the instant specification. The topcoat has the advantage of providing a controllable release of a drug in the stent (see Fig. 4, description thereof, and examples).

(Ans. 4.)

8. The Examiner finds that “[i]t would be prime [sic] facie obvious to a person of ordinary skill in the art at the time of the invention to use the topcoat composition of WO on the PBMA coated stent of Witboune [sic].” (*Id.*)
9. The Examiner finds that the motivation to combine the references “is to control the drug release rate.” (*Id.*)
10. Pacetti describes interpenetrating polymers as polymers comprising two or more networks which are at least partially interlaced on a molecular scale to form chemical and physical bonds between the networks. One way of forming the network, according to Pacetti, is blending a hydrophilic additive such as PEG with a hydrophobic additive, such as polyurethane, followed by curing. (Pacetti, 7.)

11. Pacetti further indicates that PBMA is a hydrophobic additive. (Pacetti, 8.)

ISSUE

The Examiner concludes that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to use the topcoat composition of Pacetti on the PBMA coated stent of Whitbourne. (Ans. 4.) The Examiner argues that the elected species of the biobeneficial component, poly(ethylene glycol)-co-PBMA-co-poly(ethylene glycol) (or PEG-PBMA-PEG), reads on the interpenetrating polymer of Pacetti, based on Appellant's definition of a block copolymer. (*Id.*)

Appellant contends that the elected species of PEG-PBMA-PEG does not read on the interpenetrating polymer of Pacetti, because the interpenetrating polymer of Pacetti fails to meet Appellant's definition of block copolymer. (App. Br. 7-9.)

The issue is: Does the elected species of the biobeneficial component, PEG-PBMA-PEG, read on the interpenetrating polymer of Pacetti, alternatively, does the interpenetrating polymer of Pacetti meet Appellant's definition of the block copolymer of the elected species?

A threshold issue in this case is whether Pacetti qualifies as prior art in view of a Statement of Common Ownership filed by Appellant?

PRINCIPLES OF LAW

The claims have been examined only with respect to the elected species (Office Action mailed Oct. 12, 2007, page 2). Accordingly, our decision in this appeal is limited to the obviousness or nonobviousness of the

elected subject matter. We take no position with respect to the patentability of the non-elected species or generic claims. *See Ex parte Ohsaka*, 2 USPQ2d 1460, 1461 (BPAI 1987); *Ex parte Quadranti*, 25 USPQ2d 1071, 1073 (BPAI 1992).

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a *prima facie* case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

“[O]bviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

During prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy Of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). An applicant may also act as his own lexicographer, “so long as he clearly states any special definitions of the claim terms in the patent specification,” or “‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” *Irdet Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (quoting *Bell Atl. Network*

Servs. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001)).

“Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

ANALYSIS

Claim Interpretation

In the present case Appellant has provided a specific definition for the “copolymer” and “block copolymer” of the elected species. That definition is:

The term “ABA-block copolymer” is defined as a block copolymer having moieties A and B arranged according to the general formula - {[A -]m - [B -]n - [A]p}x - , where each of m, n, p, and x is a positive integer, and m can be ≥ 2 , and n can be ≥ 2 , and p can be ≥ 2 .

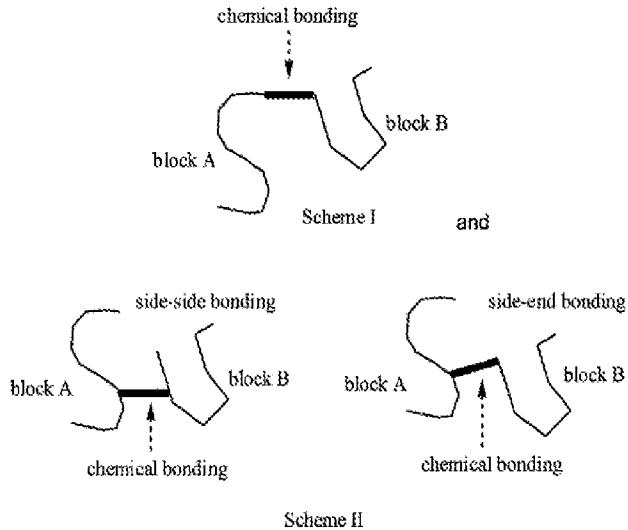
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These blocks need not be linked at the ends, since the values of the integers determining block length ensure that the individual blocks are polymers in their own right.

(Spec. 4-5.)

Appellant further clarifies this definition in the Brief, at pages 7-8, indicating that in a “block copolymer” the “chemical bonding between the two blocks can occur at the ends of the two blocks or at a position where at least one block is side-bonded to the other block, e.g., bonding via a pendant

group.” Appellant provides examples of such copolymer bonding in the schemes below, reproduced from the Brief, page 8.



We find that claim 31 recites the term “copolymer” and not the term “block copolymer.” We do acknowledge, however, that Appellant has elected a copolymer having a regular structure of three blocks, PEG-PBMA-PEG, having unspecified connectivity between the blocks. Even though the connectivity between the blocks is unspecified in the elected species, we interpret the elected species to require the polymeric structure to include regular blocks in the following relationship, PEG-PBMA-PEG.

ANALYSIS

As a threshold issue, Appellant argues that Pacetti is not prior art because Appellant’s Statement of Common Ownership filed on January 9, 2008, disqualifies Pacetti as prior art, based on 35 U.S.C. § 103(c). (Reply Br. 4.)

We are not persuaded. Appellant’s Statement of Common Ownership filed January 9, 2008, refers to the current application as “Serial No.

10/750,139” which is incorrect, as the pending application has “Serial No. 10/815,421.” Thus, the filed Statement of Common Ownership is deficient, and does not remove Pacetti as prior art under 35 U.S.C. § 103(c).

Appellant also contends that the elected species, poly(ethylene glycol)-co-PBMA-co-poly(ethylene glycol) (or PEG-PBMA-PEG), does not read on the interpenetrating polymer of Pacetti, and that the interpenetrating polymer of Pacetti fails to meet Appellant’s definition of “block copolymer.” (App. Br. 7-8.)

Appellant argues that the Examiner has interpreted the elected block copolymer to read on “a physical mixture of homopolymers of PEG and PBMA as disclosed in [Pacetti] . . . because Applicant defines a block copolymer as one that ‘needs not be linked at ends,’” but this interpretation is not a reasonable one. (App. Br. 7.) Appellant argues that the Examiner’s interpretation that the “block copolymer” as Applicant defines it “encompasses a physical mixture of two homopolymers is clearly erroneous to a person of ordinary skill in the art of polymer chemistry.” (*Id.* at 8.)

We are convinced by Appellant’s argument. Pacetti describes interpenetrating polymers as polymers comprising two or more networks which are at least partially interlaced on a molecular scale to form chemical and physical bonds between the networks. One way of forming the network, according to Pacetti, is blending a hydrophilic additive such as PEG with a hydrophobic additive, such as PBMA, followed by curing. (Pacetti, 7.)

While we acknowledge that the interpenetrating polymer of Pacetti may reasonably teach a copolymer of PEG bonded to PBMA, we do not find that the Examiner has established that Pacetti’s interpenetrating polymer

necessarily has the regular polymer structure of three blocks, PEG-PBMA-PEG.

In view of the above, we reverse the Examiner's rejection with respect to the elected species, PEG-PBMA-PEG. Again, our decision in this appeal is limited to claims directed to the elected subject matter. We take no position with respect to the patentability of the non-elected species or generic claims.

CONCLUSION OF LAW

The Appellant's filed Statement of Common Ownership is deficient, and unable to remove Pacetti as prior art under 35 U.S.C. § 103(c).

Appellant has shown that the interpenetrating polymer of Pacetti does not read on the elected species, PEG-PBMA-PEG, and the interpenetrating polymer of Pacetti does not meet Appellant's definition of block copolymer of the elected species.

The obviousness rejection as to the elected species, PEG-PBMA-PEG, is reversed.

REVERSED

cdc

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